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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/685,809
Filing Date: October 16, 2003
Appellant(s): WOO, LOUIS

Louis Woo
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 5/22/2009 appealing from the Office action mailed 2/24/2009.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

2002/0066453 A1	Ciaglia	6-2002
3,363,629	Kuhn	1-1968

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ciaglia et al (US 2002/0066453 A1) in view of Kuhn (3,363,629).

With regards to claim 1, Ciaglia discloses (figures 2-4) a tracheostomy dilator (10) comprising: a patient end region (20), said patient end region being curved (pp[0019]), tapered and adapted for insertion through a tracheostomy to expand the tracheostomy as it is inserted; and a handle region (12) at an end of the dilator opposite said patient end region. However, Ciaglia does not explicitly disclose wherein said handle region is curved in an opposite sense from said patient end region. (Provisions are provided (pp[0006, 0019]) for the handle to be curved in an opposite direction of the distal portion. Since, as pointed out in appellants appeal brief of 5/29/2008 and 11/10/2008, Ciaglia discloses (paragraph [0019]) :"The curvature of curved tapered distal portion 16 may be a series of curves of different radii, or a complex curve, from distal end 20 **at least** to demarcation 22. … While not susceptible of a precise mathematic definition, it is preferred that the curvature be complementary to the curvature of conventional curved tracheostomy tubes.").

Kuhn discloses (figure 1) an endotracheal catheter wherein said handle region (for insertion of the device (1)) is curved in an opposite sense from said patient end region (9). The tracheostomy tube of Ciaglia (pp[0019]), the instant invention and the endotracheal catheter of Kuhn all provide an insertion end (or patient end region) for connection into the trachea for assisting in the breathing process. The tracheostomy dilator of Ciaglia and the claimed invention both provide access to the trachea for insertion of a tracheostomy tube. Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the tracheostomy dilator of Ciaglia as disclosed by the curved endotracheal catheter of Kuhn for easy insertion without damage to the vocal cavity and (damage) in the trachea (Kuhn, column 1, lines 22-54).

With regards to claim 11, Ciaglia (figures 2-4) disclose a tracheostomy dilator (as for claim 1) comprising one end providing a handle region and an opposite end providing a flexible (Ciaglia, pp[0006]), tapered patient end region for insertion to the trachea, However, Ciaglia does not explicitly disclose wherein said dilator is smoothly curved along substantially its entire length with an S shape.

Kuhn teaches (figure 1) an endotracheal catheter which is smoothly curved along substantially its entire length with an S shape. The tracheostomy tube of Ciaglia (pp[0019]), of the instant invention and the endotracheal catheter of Kuhn all provide an insertion end (or patient end region) for connection into the trachea for assisting in the breathing process. The tracheostomy dilator of Ciaglia and of the claimed invention both provide access to the trachea for insertion of a tracheostomy tube. Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the tracheostomy dilator of Ciaglia as disclosed by the curved endotracheal catheter of Kuhn for easy insertion without damage to the vocal cavity and (damage) in the trachea (Kuhn, column 1, lines 22-54).

With regards to claim 12, Ciaglia (figures 2-4) discloses a tracheostomy dilator (as for claims 1 and 11 above) comprising: a patient end region (20), said patient end region tapering along its length; an intermediate region (16), said intermediate region tapering along its length substantially less than said patient end region; and a handle end region (112 and 12 of figures 1 and 2), said handle end region having a substantially constant diameter along its length, wherein said dilator has a passage extending within it and opening at a tip of said patient end region to accommodate a guide member (40) along which said dilator is inserted to the trachea, wherein the wall thickness of said patient end region reduces towards a patient end tip such as to form a smooth transition with an outer surface of said guide member (figure 3). However, Ciaglia does not explicitly disclose wherein said dilator is curved along substantially its entire length to an S shape so that the dilator can be held in the hand and inserted into the trachea ergonomically.

Kuhn teaches (figure 1, column 1, lines 35-54) an endotracheal catheter which is smoothly curved along substantially its entire length with an S shape. The tracheostomy tube of Ciaglia (pp[0019]), the tracheostomy tube of the instant invention and the endotracheal catheter of Kuhn all provide an insertion end (or patient end region) for connection into the trachea for assisting in the breathing process. The tracheostomy dilator of Ciaglia and of the tracheostomy dilator claimed invention both provide access to the trachea for insertion of a tracheostomy tube. Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the tracheostomy dilator of Ciaglia as taught by the S-shaped endotracheal catheter of Kuhn (Kuhn, column 1, lines 45-48) for providing the advantage of being introduced comparatively easily and with out damage into the trachea.

(10) Response to Argument

Appellant indicates in the current Appeal Brief:

“Independent claim 1 recites that the handle region of the claimed tracheostomy dilator is curved in an opposite sense from the patient end region.

Independent claim 11 requires that the dilator be smoothly curved along substantially its entire length with an S shape.

Independent claim 12 requires that the dilator be curved substantially along its entire length to a S shape so that the dilator can be held in the hand and inserted into the trachea ergonomically.”

Appellant argues that the curved portions of the instant device is patentable over the relied upon art of record. Appellant has previously pointed out in the appeal brief of 5/29/2008 page 10, Ciaglia discloses (paragraph [0019]) :"The curvature of curved tapered distal portion 16 may be a series of curves of different radii, or a complex curve, from distal end 20 at least to demarcation 22.

With regards to claim 1, appellant argues that Ciaglia discloses a “linear shaft” and points to Ciaglia(pp[0006 and 0019]) to support the argument. However, Ciaglia pp[0006 and 0019] implicitly provides for the argued language of claim 1, since a multi-curved distal or patient end region (Ciaglia, pp[0019]) combined with a **generally** linear shaft (Ciaglia , pp[0006]) will inherently have a “handle region curved in an opposite sense from said patient end region”. Furthermore, Ciaglia provides two implied modifications ((1) a **generally** liner shaft and (2) a multi- curved distal or patient end) to the tracheostomy dilator that given a reasonable interpretation would disclose appellants' instant tracheostomy dilator as claimed in claim 1 namely “curved in an opposite sense from the patient end region”.

To further support the 103 rejection of claim 1, the office points to the device of Kuhn (figure 1) which clearly discloses a multi-curved endotracheal device with a “handle region curved (2) in an opposite sense from said patient end region (9)”.

Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the tracheostomy dilator of Ciaglia as disclosed by Kuhn for easy insertion without damage to the vocal cavity and the trachea (Kuhn, column 1, lines 22-54). Since it has been held that a change in the shape of a prior art device is a design consideration within the skill of the art. In re Dailey, 357 F.2d 669, 149 USPQ 47 (CCPA 1966).

With regards to claims 11 and 12, appellant argues that Ciaglia is not S-shaped. To support the 103 rejection of claims 111 and 12, the office points to the device of Kuhn (figure 1) which clearly discloses a S-shaped multi-curved endotracheal for providing the advantage of being introduced comparatively easily and with out damage into the trachea (Kuhn, column 1, lines 45-48).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the tracheostomy dilator of Ciaglia as disclosed by Kuhn for easy insertion without damage to the vocal cavity and the trachea (Kuhn, column 1, lines 22-54). Since it has been held that a change in the shape of a prior art device is a design consideration within the skill of the art. In re Dailey, 357 F.2d 669, 149 USPQ 47 (CCPA 1966).

In response to appellant's argument that Kuhn is “completely different” or nonanalogous art, it has been held that a prior art reference must either be in the field of appellant’s endeavor or, if not, then be reasonably pertinent to the particular problem with which the appellant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, the instant invention is classified in 128/207.29 along with the prior art device of Ciaglia. Kuhn is a prior art reference classified in 128/207.15. Both classifications 128/207.29 and 128/207.15 are subclasses of classification 128/207.14, therefore the prior art references are in the field of appellant’s endeavor and reasonably pertinent to the particular problem with which the appellant was concerned.

In response to appellant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the appellant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

In response to appellant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the knowledge is generally available to one of ordinary skill in the art in classification 128/207.14, which includes both prior art classifications 128/207.29 and 128/207.15. Furthermore, it has been held that a change in the shape of a prior art device is a design consideration within the skill of the art. In re Dailey, 357 F.2d 669, 149 USPQ 47 (CCPA 1966). In this case the only difference between the prior art dilator of Ciaglia and the instant device is the shape which is disclosed by the prior art of Kuhn.

In response to appellant's argument that the dilators of the instant invention and prior art reference Ciaglia cause damage the vocal cavity during use, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. It is further noted that instant invention and both of the prior art inventions avoid damage the vocal cords which is part of an intended use of all of the devices.

In response to appellant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Michael J Anderson/

Examiner, Art Unit 3767

Conferees:

/Kevin C. Sirmons/

Supervisory Patent Examiner, Art Unit 3767

/Thomas C. Barrett/

Supervisory Patent Examiner, Art Unit 3775